



Development of a panel of U.S. adult tobacco users to inform tobacco regulatory science

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ABSTRACT

The National Panel of Tobacco Consumer Studies (TCS Panel) is a probability-based panel of about 4,000 U.S. adult cigarette, cigar, and smokeless tobacco users developed by the U.S. Food and Drug Administration's Center for Tobacco Products to conduct observational and experimental studies to inform tobacco regulatory activities. This paper describes the methods and characteristics of the current panel. The TCS Panel employed a stratified 4-stage sample design and in-person screening of U.S. sampled households. Selected eligible adults participated in an enrollment interview and completed a baseline survey assessing tobacco use behaviors to enroll in the Panel; 3,893 individuals were enrolled from September 2016–August 2017. Replenishment occurred from July 2019–December 2019 with 2,260 new members, for a current panel of 3,929 members. Demographic and tobacco use characteristics of the current panel were analyzed in 2020. Most demographic characteristics of the TCS Panel are similar to those of U.S. tobacco users in the 2018 National Health Interview Survey, suggesting a lack of systematic bias in the Panel. Small, but statistically significant, differences were observed in the proportion of 18- to 25-year-olds; high school diploma and bachelor's degree/higher; never married and married ($p < 0.05$ for all). The TCS Panel appears to be representative of U.S. cigarette, cigar, and smokeless tobacco users; such panels can be a feasible method for conducting tobacco regulatory science research. The TCS Panel has been used to field studies examining purchasing behaviors, receipt and use of free samples/coupons, and the impact of a hypothetical tobacco product standard.

1. Introduction

In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act, which gives the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products broad authority to regulate the manufacturing, distribution, and marketing of tobacco products. This authority includes developing product standards, reviewing premarket applications for new and modified risk tobacco products, requiring new health warnings, and enforcing advertising and promotion restrictions (U.S. FDA, 2022). The FDA was given immediate jurisdiction over cigarettes, smokeless tobacco, cigarette tobacco, and roll-your-own

tobacco, and in 2016, finalized a deeming rule extending its regulatory authorities to cover all tobacco products, including e-cigarettes, cigars, hookah, pipe tobacco, nicotine gels, and dissolvables (Ashley and Backinger, 2012; U.S. FDA, 2020). The FDA regulates tobacco products based on a population health standard that considers the risks and benefits of tobacco products on users and nonusers, and applies existing scientific evidence to inform regulatory decisions and actions (Ashley and Backinger, 2012; Backinger et al., 2016). The FDA supports and conducts research through various mechanisms, including collaborations with other government agencies, academic institutions, and contract research organizations, to advance the tobacco regulatory science

Abbreviations: TCS Panel, National Panel of Tobacco Consumer Studies; FDA, Food and Drug Administration; NHIS, National Health Interview Survey; PATH, Population Assessment of Tobacco and Health; IRB, Institutional Review Board; PSUs, primary sampling units; PPS, probability proportional to size; CBGs, census block groups; SES, socioeconomic status.

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evidence base (Ashley and Backinger, 2012; Frechtling et al., 2021).

In 2012, the FDA began designing its own panel of U.S. adult tobacco users to conduct observational and experimental tobacco regulatory science research studies. The panel was designed to have characteristics that were not present in the existing commercial online panels (Craig et al., 2013; American Association for Public Opinion Research, 2010), including a rigorous probability-based design to ensure that panel participants represented the sociodemographic spectrum of tobacco users in the U.S., an adequate sample of tobacco users with power to detect changes in key outcomes, and the flexibility to rapidly field research studies on diverse emerging and priority topics. Existing online panels were often nonprobability samples of the population, limiting generalizability of study findings even when using weight-adjusted estimates (Craig et al., 2013), and available probability-based online panels were designed to represent the general U.S. population rather than the sociodemographic spectrum of tobacco users (Nancarrow and Cartwright, 2007). While national surveys such as the National Health Interview Survey (NHIS) and Population Assessment of Tobacco and Health (PATH) Study have been used to monitor behaviors of adult tobacco users in the U.S., they are limited by their frequency and timing of data collection (Centers for Disease Control and Prevention, 2020; National Addiction and HIV Data Archive Program, 2022). Additionally, the PATH Study, which is a longitudinal cohort study, is not designed for conducting experimental research studies which may influence participants' behavior (National Addiction and HIV Data Archive Program, 2022).

The FDA contracted with RTI International to develop a probability-based panel of approximately 4,000 U.S. adult cigarette, cigar, and smokeless tobacco users. The panel, known as the National Panel of Tobacco Consumer Studies (hereafter referred to as the TCS Panel), was developed using a national address-based sampling frame, in-person screening of sampled U.S. households, and in-person recruitment of eligible adult household members. Panel members could be invited to participate in up to 8 observational and experimental studies over a 3-year period. The TCS Panel has been used to field studies examining tobacco purchasing behaviors, receipt and use of free samples and coupons, and perceptions of a hypothetical tobacco product standard. This paper describes the TCS Panel's sample design, and screening, recruitment, and enrollment processes. It also describes characteristics of the current panel overall and by tobacco product use.

2. Methods

2.1. TCS Panel

The TCS Panel was designed to be nationally representative of the adult U.S. cigarette, cigar, and smokeless tobacco user population, although panel members may also use other tobacco products. The study design, protocol, and data collection were approved by RTI International's Institutional Review Board (IRB)^a and Office of Management and Budget. The TCS Panel methods met RTI International's guidelines for protection of human subjects concerning their safety and privacy. A total of 3,893 individuals were enrolled in the TCS Panel from September 2016–August 2017. Unforeseen delays with administrative clearances resulted in an approximately 18-month interval between when the earliest participants were recruited and when they were invited to participate in the first study in April 2018, resulting in a study response rate of approximately 45%. The decision was made to disenroll panel members who did not respond to the first study unless they opted to continue participating. Subsequently, the TCS Panel was replenished from July 2019–December 2019 with 2,260 new panel members, resulting in a total of 3,929 panel members in the current panel. There

^a Per an IRB Authorization Agreement between RTI International and FDA, where RTI International IRB was the IRB of record.

were no significant differences in the composition of the current panel and the base panel with respect to age, race/ethnicity, sex, education, marital status, household income, and geographic region, or use of cigarettes, cigars, hookah tobacco, or pipe tobacco. The current panel has a smaller proportion of smokeless tobacco users ($p < 0.05$) and greater proportion of e-cigarette users ($p < 0.05$) than the original panel (Supplemental Table 1).

2.2. Study design

The target population included U.S. adults aged 18 years and older in housing units and noninstitutionalized group quarters who use cigarettes, cigars, and smokeless tobacco. A stratified 4-stage sampling design was used. At the first stage, primary sampling units (PSUs) were selected. PSUs were created by combining small contiguous counties so that the resulting PSU had at least 2,000 tobacco users, and by dividing large counties with more than 31,000 tobacco users into smaller areas. The number of tobacco users in each county was estimated using the National Adult Tobacco Survey (2007–2012) (Centers for Disease Control and Prevention, 2016) and the American Community Survey (2006–2010) (U.S. Census Bureau, 2021). In this way, 3,778 customized PSUs were created. Of these, 80 were selected using a probability proportional to size (PPS) method. Within each selected PSU, 3 census block groups (CBGs) were selected at the second stage, also using a PPS method. At the third stage, 152 housing units within each CBG were selected. The fourth stage consisted of selecting 1 eligible adult tobacco user per housing unit using predetermined selection probabilities from 4 design strata defined by crossing socioeconomic status (low SES vs. non-low SES) and age group (18–25 vs. 26 +). Each design stratum had a target sample size. Households were sampled primarily via address-based sampling, with the sample augmented to account for under coverage using field enumeration and frame-linking (McMichael et al., 2008; Shook-Sa et al., 2016). During panel replenishment, the same 80 PSUs were selected at the first stage; 2 CBGs per PSU were selected at the second stage; approximately 150 housing units were selected per CBG at the third stage; and 1 eligible adult tobacco user was selected per housing unit.

To be eligible, individuals had to meet the following criteria: aged 18 years or older; full-time resident of the sampled address in the 50 states or District of Columbia; non-active duty military; English- or Spanish-speaking; and current (every day or some days) user of at least one of the following: cigarettes, cigars, and smokeless tobacco products. To meet the target sample sizes in each design stratum formed by age group and SES, adult tobacco users aged 18–25 years, specifically those with non-low SES, were oversampled due to the lower prevalence of cigarette use among this subgroup (U.S. Department of Health and Human Services, 2012). Smokeless tobacco users were also assigned higher probabilities of selection to ensure adequate sample for analyses.

Power analyses determined that approximately 4,000 panel members and target sample sizes within each design strata could achieve reasonable statistical precision. For proportion estimates in domains such as SES, age, race/ethnicity, sex, and tobacco products, the relative standard errors were under 6% assuming a proportion estimate around 0.5.

2.3. Screening of sampled households

A brief screening survey and a \$2 cash incentive were mailed to sampled households with complete mailing addresses to collect information on the number of adult household members and whether any adults in the household use cigarettes, cigars, and/or smokeless tobacco. A postcard reminder was sent 2 weeks later to all sampled households that received the screener. A second screener was mailed to non-responding households 2 weeks after the postcard reminder. In-person field screening was conducted with households reporting at least one adult tobacco user (user of cigarettes, cigars, and/or smokeless tobacco

products) on the screener and households with unknown potential eligibility (i.e., did not return screener, incomplete mailing address, incomplete screener responses). Ten percent of households identified as ineligible based on screener responses were also selected for in-person household screening for quality control purposes.

During in-person field screening, which took about 10 min, interviewers collected demographic and tobacco use information for each adult household member. An algorithm was developed such that an eligible adult tobacco user was randomly selected to join the panel based on predetermined selection probabilities in each design domain estimated from the 2010–2011 Tobacco Use Supplement to the Current Population Survey (Brewer, 1963; National Cancer Institute, 2021). Users in the 18–25 and non-low SES domain had the highest probability of selection, smokeless tobacco users had the second highest probability of selection, followed by users in the 18–25 and low SES domain, the 26 and older and non-low SES domain, and the 26 and older and low SES domain.

2.4. Recruitment and enrollment

Selected eligible adults completed an enrollment interview and a baseline survey, which took about 10 min each. During the enrollment interview, field interviewers verified eligibility information collected during screening, as needed; obtained informed consent and contact information; and identified mode of participation for panel studies. Panel members could participate in future panel studies either by web using personal devices or a loaned study tablet, or by mail. After the enrollment interview, panel members responded to a baseline questionnaire that collected detailed information about participants' cigarette, cigar, and smokeless tobacco use, such as frequency of use, intentions to quit within the next 30 days, use of other tobacco products, and dependence. Information on use of e-cigarettes, hookah tobacco, and pipe tobacco was also collected. Panel members participating via web were instructed on how to access the TCS Panel website and completed the baseline questionnaire (in the field interviewer's presence) using personal devices or loaned study tablet. For panel participants enrolled as mail participants, field interviewers used their own tablet to administer the baseline questionnaire. Individuals received a total of \$35 cash for completing both enrollment and baseline questionnaires. Enrollment and baseline questionnaires were based on tobacco use questions from the National Health Interview Survey (Centers for Disease Control and Prevention, 2020) and Tobacco Use Supplement – Current Population Survey. (National Cancer Institute, 2021).

2.5. Field interviewers

All TCS Panel field interviewers completed a comprehensive 4-day, classroom-based training program and were certified on data collection protocols and systems before beginning work. Bilingual interviewers received an additional half-day training on Spanish-language protocols.

2.6. Response rates

Response rates were computed in accordance with American Association for Public Opinion Research guidelines (American Association for Public Opinion Research, 2016). For the overall TCS Panel, the weighted response rate for the household screeners was 77.8% (unweighted: 80.0%). Among screened sampled households, the weighted response rate was 80.7% for the enrollment and baseline questionnaires (unweighted: 82.1%).

2.7. Statistical analysis

We calculated weighted prevalence estimates and 95% confidence intervals of demographic and tobacco use characteristics of the current

panel overall, and stratified by cigarette, cigar, and smokeless tobacco use status. Users of multiple tobacco products were included in the analyses for each tobacco product that they currently use. Summary statistics were calculated in SAS® software version 9.4 (SAS Institute, Cary, NC). To understand potential bias due to sample composition, we compared demographic characteristics of the current TCS Panel with a subsample of the 2018 NHIS respondents who were cigarette, cigar, and smokeless tobacco users using adjusted Wald tests, with a Bonferroni adjustment, estimated in SUDAAN® version 11 (RTI International, Research Triangle Park, NC). All analyses accounted for the complex survey design and sample weights were adjusted for nonresponse, coverage, and large or extreme weights. All analyses were conducted in 2020. Missing values were excluded from analyses.

3. Results

3.1. Participant characteristics

Table 1 reports demographic characteristics of the current TCS Panel. Many TCS Panel participants are older adults; 40.0% are 50 years or older. TCS Panel participants are most frequently non-Hispanic White (70.2%), male (60.3%), married (51.6%), and have a high school diploma or GED (37.6%). More than 60% have an annual household income less than \$50,000.

Most demographic characteristics of the current TCS Panel are similar to those of cigarette, cigar, and smokeless tobacco users in the 2018 NHIS with the exception of age, education, and marital status (Table 1). Statistically significant differences were observed with regards to the proportion of 18- to 25-year-olds (TCS: 14.4%, NHIS: 8.9%; $p < 0.05$), high school diploma or GED (TCS: 37.6%, NHIS: 33.5%; $p < 0.05$), bachelor's degree or higher (TCS: 14.6%, NHIS: 18.1%; $p < 0.05$), never married (TCS: 27.7%, NHIS: 36.3%; $p < 0.05$), and married (TCS: 51.6%, NHIS: 43.7%; $p < 0.05$).

Demographic distributions for TCS Panel participants are reported in Table 2, separately for users of cigarettes, cigars, and smokeless tobacco. Compared with cigar users and smokeless tobacco users, cigarette users skew more heavily toward older users, with approximately 41.0% of cigarette users being 50 years or older and only 12.9% in the 18- to 25-year-old category. Compared to cigarette users, the proportion of smokeless tobacco users in the older age groups is lower, and the proportion in the younger age groups is higher. By comparison, the age distribution of cigar users is more uniform, with approximately equal representation in each age group.

The distribution of race/ethnicity for cigarette, cigar, and smokeless tobacco users in the TCS Panel is heavily skewed toward non-Hispanic White, especially among smokeless tobacco users where 81.2% of all users are non-Hispanic White. A higher proportion of cigar users are non-Hispanic Black (19.0%) and Hispanic (13.8%) relative to cigarette and smokeless tobacco users. Males represent the majority of cigarette (54.1%), cigar (73.5%), and smokeless tobacco users (92.7%).

The majority of cigarette, cigar, and smokeless tobacco users in the TCS Panel have less than a bachelor's degree (i.e., less than high school, high school/GED, or some college). A clear gradient is observed with respect to annual household income, with the highest proportion of users occurring in the lowest income categories.

3.2. Tobacco use behaviors

Tobacco use behaviors of the TCS Panel participants are reported in Table 3. Use every day versus some days varies by tobacco product, with 81.0% of cigarette users reporting use every day, compared with only 20.0% of cigar users and 61.8% of smokeless tobacco users.

Time to first use after waking also varies, with larger proportions of cigarette users reporting first use within 5 min (28.1%) and from 6 to 30 min (35.6%) than cigar users (10.5%, 11.6% respectively) and smokeless tobacco users (10.9%, 22.5% respectively). More than two-thirds of

Table 1
Demographic Characteristics of the 2016–2019 Tobacco Consumer Studies Panel and 2018 National Health Interview Survey.

Characteristic	TCS Panel (n = 3,929)		NHIS (n = 4,745)		P-Value
	n ^a	% ^b (95% CI) ^c	n ^a	% ^b (95% CI) ^c	
Age (years)					
18–25	707	14.4 (13.1–15.6)	314	8.9 (7.7–10.2)	0.000
26–34	671	18.5 (16.9–20.0)	795	19.7 (18.3–21.0)	0.263
35–49	1,052	27.2 (25.5–28.9)	1,275	29.3 (27.6–31.0)	0.087
≥50	1,499	40.0 (38.1–41.9)	2,361	42.1 (40.4–43.8)	0.100
Race/Ethnicity					
White, non-Hispanic	2,492	70.2 (68.6–71.8)	3,481	70.1 (68.1–72.2)	0.958
Black, non-Hispanic	750	12.2 (11.3–13.1)	555	11.9 (10.5–13.4)	0.797
Hispanic	424	9.6 (8.5–10.7)	389	11.0 (9.5–12.5)	0.120
Other, non-Hispanic	231	8.1 (6.9–9.2)	320	6.9 (5.8–8.0)	0.168
Sex					
Male	2,238	60.3 (58.4–62.1)	2,838	63.1 (61.3–64.8)	0.031
Female	1,690	39.7 (37.9–41.6)	1,907	36.9 (35.2–38.7)	0.031
Education					
Less than high school	550	15.2 (13.9–16.6)	707	15.1 (13.8–16.5)	0.944
High school/GED	1,561	37.6 (35.8–39.5)	1,546	33.5 (31.8–35.3)	0.001
Some college ^d	1,307	32.6 (30.8–34.4)	1,592	33.3 (31.5–35.0)	0.602
Bachelor's degree or higher	508	14.6 (13.2–15.9)	884	18.1 (16.7–19.5)	0.000
Marital Status					
Never married	1,256	27.7 (26.1–29.3)	1,625	36.3 (34.5–38.1)	0.000
Married	1,770	51.6 (49.7–53.5)	1,660	43.7 (41.8–45.6)	0.000
Divorced or separated	739	17.1 (15.7–18.4)	1,124	15.9 (14.8–16.9)	0.171
Widowed	161	3.6 (2.9–4.3)	328	4.2 (3.6–4.8)	0.194
Annual Household Income ^{e,f}					
<\$30,000	1,728	40.5 (38.7–42.3)	—	—	
\$30,000–\$49,999	888	21.9 (20.3–23.4)	—	—	
\$50,000–\$74,999	494	12.8 (11.5–14.0)	—	—	
\$75,000–\$99,999	300	9.0 (7.8–10.1)	—	—	
≥\$100,000	314	10.2 (9.0–11.4)	—	—	
≥\$30,000 ^g	205	5.7 (4.7–6.7)	—	—	
Geographic Region					
Northeast	593	16.6 (15.9–17.3)	685	15.6 (14.1–17.1)	0.242
Midwest	1,198	25.1 (24.3–25.9)	1,298	26.4 (24.6–28.2)	0.202
South	1,608	40.6 (39.6–41.5)	1,867	40.1 (38.1–42.2)	0.714
West	530	17.7 (16.9–18.5)	895	17.9 (16.2–19.5)	0.883

Notes:
Boldface indicates statistically significant difference between TCS Panel and NHIS for the specified characteristic. Threshold for significance was $p < 0.05$ and was adjusted using the Bonferroni correction for multiple comparisons: $p < 0.013$ for Age, Race/Ethnicity, Education, Marital Status, and Geographic Region; $p < 0.025$ for Sex.
 a: Unweighted sample size.
 b: Weighted proportion.

c: 95% CI denotes two-sided 95% confidence interval.
 d: Includes vocational/technical training and 2-year college degree (associate's degree).
 e: The annual household income categories reported here are those that were collected for the TCS Panel. Income categories in the NHIS were not comparable, therefore, a test for differences for income was not conducted.
 f: Missing annual household income data for TCS Panel were imputed using median household income in the census block group housing unit.
 g: Respondents in the TCS Panel who did not provide total combined income of all members of their family during the past 12 months were asked "Would you say the total combined income of all members of your household during the past 12 months was less than \$30,000 or \$30,000 or more?".
 TCS Panel, Tobacco Consumer Studies Panel.
 NHIS, National Health Interview Survey.

cigar users (69.2%) and almost half of smokeless tobacco users (46.4%) report waiting more than 1 h before first use. A majority of users of each tobacco product report that they are not planning to stop using within the next 30 days (cigarettes 79.3%, cigars 72.9%, smokeless tobacco 81.4%).

Use of multiple tobacco products is less common among cigarette users (37.4%) than among cigar users (76.9%) and smokeless tobacco users (50.8%). Among cigarette users who use one or more additional tobacco products, cigars (21.3%) are the most commonly used. Cigarettes are the most commonly used other tobacco product among cigar users (62.5%) and smokeless tobacco users (36.1%). Among poly tobacco users, e-cigarette use is relatively common, reported by 17.5% of cigarette users, 22.4% of cigar users, and 17.0% of smokeless tobacco users.

4. Discussion

This paper presents an overview of the rationale, design, conduct, and characteristics of the TCS Panel, a probability-based panel of cigarette, cigar, and smokeless tobacco users in the U.S. developed by the FDA for fielding tobacco regulatory science studies. Although commercial online panels have been used to study tobacco use behavior, the FDA developed its own panel to provide flexibility in fielding tobacco regulatory research studies in a rigorous, relatively large, probability-based sample of U.S. adult tobacco users. The TCS Panel, which uses a 4-stage, address-based sampling method with in-person screening and recruitment, is designed to represent the sociodemographic spectrum of cigarette, cigar, and smokeless tobacco users in the U.S.

Most characteristics of TCS Panel participants are similar to characteristics of cigarette, cigar, and smokeless tobacco users in the 2018 NHIS, suggesting a lack of systematic bias in the estimates produced by the TCS Panel. As expected, the TCS Panel has a higher proportion of tobacco users aged 18–25 years, who were purposively oversampled in the TCS Panel, compared with the NHIS. The TCS Panel also has a higher proportion of participants with a high school diploma/GED, lower proportion with a bachelor's degree, lower proportion of never married, and a higher proportion of married tobacco users than the NHIS. Overall, the TCS Panel appears to be representative of U.S. cigarette, cigar, and smokeless tobacco users.

Another key strength of the TCS Panel is its mixed-mode design that allows for participation in future panel studies by web or mail. By offering a mail option for participants who were unwilling or unable to participate in future studies by web, the TCS Panel minimizes the potential for coverage and nonresponse bias. The rigorous sampling and recruitment approach, combined with the multi-mode design, enables FDA to reach a representative sample of adult cigarette, cigar, and smokeless tobacco users with whom to field observational and experimental tobacco regulatory science studies.

The TCS Panel has been used to field studies examining tobacco product purchasing behaviors, brand loyalty, and use of price promotions; receipt and use of free samples and discount coupons for cigarettes, cigars, smokeless tobacco, e-cigarettes, and hookah tobacco; and

Table 2
Demographic Characteristics of 2016–2019 Tobacco Consumer Studies Panel by Cigarette, Cigar, and Smokeless Tobacco Use.

Characteristic	Cigarette Users ^{e,f} (n = 3,146)		Cigar Users ^{e,g} (n = 1,161)		Smokeless Tobacco Users ^{e,h} (n = 664)	
	n ^a	% ^b (95% CI) ^c	n ^a	% ^b (95% CI) ^c	n ^a	% ^b (95% CI) ^c
Age (years)						
18–25	521	12.9 (11.6–14.2)	346	23.8 (21.0–26.6)	131	17.5 (13.9–21.1)
26–34	534	18.4 (16.6–20.1)	251	22.9 (19.8–26.0)	123	21.1 (17.3–24.9)
35–49	853	27.8 (25.8–29.7)	282	25.7 (22.7–28.8)	198	30.6 (26.5–34.8)
≥50	1,238	41.0 (38.8–43.1)	282	27.5 (24.3–30.8)	212	30.8 (26.7–34.9)
Race/Ethnicity						
White, non-Hispanic	1,971	69.5 (67.6–71.4)	572	58.6 (55.2–61.9)	530	81.2 (77.6–84.8)
Black, non-Hispanic	595	11.9 (10.9–13.0)	323	19.0 (16.7–21.2)	55	6.1 (4.3–7.9)
Hispanic	354	10.1 (8.9–11.4)	171	13.8 (11.3–16.3)	44	5.4 (3.5–7.2)
Other, non-Hispanic	197	8.4 (7.1–9.8)	85	8.6 (6.5–10.7)	34	7.3 (4.5–10.2)
Sex						
Male	1,596	54.1 (51.9–56.2)	790	73.5 (70.6–76.5)	597	92.7 (90.6–94.7)
Female	1,550	46.0 (43.8–48.1)	371	26.5 (23.5–29.4)	66	7.4 (5.3–9.4)
Education						
Less than high school	464	16.3 (14.7–17.9)	149	13.8 (11.2–16.3)	106	15.7 (12.5–18.9)
High school/GED	1,283	39.0 (36.9–41.1)	455	36.5 (33.1–39.8)	267	38.7 (34.4–43.0)
Some college ^d	1,048	32.4 (30.4–34.3)	396	32.9 (29.6–36.2)	201	31.8 (27.5–36.2)
Bachelor's degree or higher	349	12.4 (11.0–13.8)	161	16.9 (14.1–19.6)	89	13.8 (10.6–16.9)
Marital Status						
Never married	981	27.0 (25.1–28.8)	521	37.5 (34.2–40.8)	187	26.4 (22.4–30.5)
Married	1,362	50.3 (48.1–52.4)	459	47.4 (43.8–50.9)	369	59.1 (54.6–63.5)
Divorced or separated	656	18.9 (17.3–20.5)	165	13.8 (11.3–16.3)	87	11.4 (8.7–14.0)
Widowed	145	3.9 (3.1–4.7)	16	1.4 (0.6–2.1)	20	3.1 (1.6–4.7)
Annual Household Income ⁱ						
<\$30,000	1,469	42.8 (40.8–44.9)	548	44.6 (41.2–48.1)	256	37.5 (33.1–41.8)
\$30,000–\$49,999	720	22.6 (20.8–24.3)	267	21.8 (18.8–24.8)	128	17.8 (14.4–21.2)
\$50,000–\$74,999	386	12.8 (11.4–14.2)	127	10.0 (8.1–11.9)	105	15.1 (12.1–18.1)
\$75,000–\$99,999	232	9.0 (7.6–10.3)	74	7.8 (5.8–9.7)	56	9.2 (6.6–11.8)
≥\$100,000	187	7.3 (6.1–8.5)	99	12.5 (9.9–15.1)	77	14.1 (10.8–17.4)
≥\$30,000 ^j	152	5.5 (4.5–6.6)	46	3.3 (2.2–4.4)	42	6.3 (3.8–8.7)
Geographic Region						
Northeast	465	16.6 (15.5–17.6)	202	18.3 (15.9–20.7)	86	10.9 (8.5–13.2)
Midwest	963	24.9 (23.8–26.0)	338	23.5 (21.1–25.9)	183	24.9 (21.4–28.5)
South	1,284	40.8 (39.5–42.1)	455	40.1 (37.0–43.1)	298	44.3 (40.2–48.4)
West	434	17.7 (16.6–18.9)	166	18.2 (15.7–20.6)	97	19.9 (16.2–23.7)

Notes:

a: Unweighted sample size.

b: Weighted proportion.

c: 95% CI denotes two-sided 95% confidence interval.

d: Includes vocational/technical training and 2-year college degree (associate's degree).

e: Table columns are not mutually exclusive. Users of multiple tobacco products were included in analyses for each tobacco product that they currently use.

f: Cigarette user defined as having smoked at least 100 cigarettes in entire life, and every day or some days at the time of enrollment.

g: Cigar user defined as every day or some days use of regular cigars, cigarillos, or little filtered cigars at the time of enrollment.

h: Smokeless tobacco use defined as every day or some days use of smokeless tobacco at the time of enrollment.

i: Missing annual household income data for TCS Panel were imputed using median household income in the census block group housing unit.

j: Respondents who did not provide total combined income of all members of their family during the past 12 months were asked "Would you say the total combined income of all members of your household during the past 12 months was less than \$30,000 or \$30,000 or more?".

TCS Panel, Tobacco Consumer Studies Panel.

perceptions of a hypothetical tobacco product standard. Results from these studies will increase the FDA's understanding of tobacco users' behaviors and perceptions, and inform regulatory approaches to topics such as price promotions and tobacco product standards.

A limitation of the TCS Panel is that use of e-cigarettes, hookah, and pipe tobacco were not part of the design criteria. Users of e-cigarettes, in particular, were not specifically recruited because when the TCS Panel was designed in 2012, e-cigarettes were still relatively new; the e-cigarette market was rapidly evolving with the proliferation of new brands (Zhu et al., 2014) and flavors (Kuiper et al., 2018), and continues to evolve. Users of hookah and pipe tobacco were not specifically recruited because their prevalence of use is low (Cornelius et al., 2020) and identifying sufficient numbers would have been cost prohibitive. Nonetheless, numbers of e-cigarette, hookah, and pipe tobacco users in the TCS Panel are sufficient for analysis. As reported in Supplemental Table 1, the prevalence of e-cigarette use in the TCS Panel was 16.1% (95% CI 14.7–17.5, n = 632), prevalence of hookah use was 6.2% (95% CI 5.3–7.2, n = 271), and prevalence of pipe tobacco use was 4.9% (95% CI 4.0–5.7, n = 200). Although not generalizable, data on e-cigarette,

hookah, and pipe tobacco can still inform research questions related to those products.

5. Conclusions

The FDA has collaborated with government agencies, academic institutions, contract research organizations, and others to fund and conduct research to assess the impact of FDA's regulatory authority and inform FDA's regulatory activities (Ashley and Backinger, 2012; Backinger et al., 2016; Frechtling et al., 2021; Price et al., 2020). Panels of tobacco product users that are representative of the sociodemographic spectrum of tobacco users can be a feasible method for conducting observational and experimental tobacco regulatory science research among tobacco product users.

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Table 3
Tobacco Use Behaviors of 2016–2019 Tobacco Consumer Studies Panel Participants.

Characteristic	Cigarette Users ^{d,e} (n = 3,146)		Cigar Users ^{d,f} (n = 1,161)		Smokeless Tobacco Users ^{d,g} (n = 664)	
	n ^a	% ^b (95% CI) ^c	n ^a	% ^b (95% CI) ^c	n ^a	% ^b (95% CI) ^c
Frequency of Use						
Every day	2,509	81.0 (79.3–82.6)	269	20.0 (17.3–22.6)	409	61.8 (57.4–66.2)
Some days	637	19.0 (17.4–20.7)	892	80.1 (77.4–82.7)	255	38.2 (33.8–42.6)
Number of Days Used in the Past 30 Days (among some day users)						
0	20	3.0 (1.5–4.4)	184	21.7 (18.4–25.0)	47	14.9 (9.7–20.0)
1–5	121	19.5 (15.6–23.3)	356	42.3 (38.2–46.3)	91	34.0 (27.0–40.9)
6–19	225	33.9 (29.3–38.4)	237	24.5 (21.1–27.8)	74	34.8 (27.3–42.2)
20–30	264	43.7 (38.8–48.6)	111	11.6 (8.9–14.2)	42	16.4 (11.1–21.7)
Time to First Use after Waking Up						
Within 5 min	867	28.1 (26.2–30.0)	123	10.5 (8.4–12.6)	74	10.9 (7.9–13.9)
From 6 to 30 min	1,125	35.6 (33.5–37.6)	145	11.6 (9.4–13.8)	144	22.5 (18.7–26.3)
From 31 to 60 min	538	17.4 (15.8–19.1)	113	8.8 (6.8–10.7)	131	20.2 (16.6–23.8)
Greater than 1 h	610	18.9 (17.3–20.6)	763	69.2 (65.9–72.4)	307	46.4 (41.9–50.9)
Planning to Stop Using within the Next 30 Days						
Yes	691	20.7 (19.0–22.4)	328	27.1 (24.0–30.2)	136	18.6 (15.4–21.9)
No	2,450	79.3 (77.6–81.0)	825	72.9 (69.8–76.0)	525	81.4 (78.1–84.6)
Use of ≥ 2 Tobacco Products ^h						
Yes	1,225	37.4 (35.3–39.4)	898	76.9 (73.9–79.8)	337	50.8 (46.2–55.3)
No	1,921	62.6 (60.6–64.7)	263	23.1 (20.2–26.1)	327	49.2 (44.7–53.8)
Other Tobacco Product Use						
Cigarettes ^e	—	—	727	62.5 (59.1–65.9)	248	36.1 (31.8–40.4)
Cigars ^f	727	21.3 (19.6–23.0)	—	—	194	28.7 (24.6–32.8)
Smokeless tobacco ^g	248	7.5 (6.4–8.6)	194	17.5 (14.8–20.2)	—	—
E-cigarettes ⁱ	557	17.5 (15.9–19.1)	263	22.4 (19.5–25.2)	107	17.0 (13.4–20.6)
Waterpipe or hookah ^j	194	5.6 (4.6–6.7)	184	14.6 (12.1–17.0)	43	7.4 (4.6–10.2)
Pipe tobacco ^j	152	4.7 (3.7–5.6)	152	12.6 (10.3–15.0)	51	6.7 (4.5–8.9)

Notes:

a: Unweighted sample size.

b: Weighted proportion.

c: 95% CI denotes two-sided 95% confidence interval.

d: Table columns are not mutually exclusive. Users of multiple tobacco products were included in analyses for each tobacco product that they currently use.

e: Cigarette user defined as having smoked at least 100 cigarettes in entire life, and every day or some days at the time of enrollment.

f: Cigar user defined as every day or some days use of regular cigars, cigarillos, or little filtered cigars at the time of enrollment.

g: Smokeless tobacco use defined as every day or some days use of smokeless tobacco at the time of enrollment.

h: Use of ≥ 2 tobacco products defined as current use of 2 or more of the following tobacco products: cigarettes; regular cigars, cigarillos, or little filtered cigars; smokeless tobacco; e-cigarettes; waterpipe or hookah; pipe tobacco.

i: Current e-cigarette use defined as every day or some days use of e-cigarettes at the time of enrollment.

j: For waterpipe or hookah and pipe, current use was defined as currently using these products (yes/no).

TCS Panel, Tobacco Consumer Studies Panel.

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Sherry T. Liu: Conceptualization, Writing – original draft, Supervision. **Brett R. Loomis:** Conceptualization, Writing – original draft. **Susan H. Kinsey:** Conceptualization, Writing – review & editing. **Caryn F. Nagler:** Conceptualization, Writing – review & editing. **Patrick Chen:** Formal analysis, Writing – review & editing. **Amang Sukasih:** Formal analysis, Writing – review & editing. **Martha C. Engstrom:** Conceptualization, Writing – review & editing. **Conrad J. Choiniere:** Conceptualization, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.pmedr.2022.101898>.

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